REMARKS

In the Office Action dated October 5, 2004, claims 1-22 were examined with the result that all claims were rejected. In response, Applicant has canceled claims 17-22 and rewritten claim 12. In view of the above amendments and following remarks, reconsideration of this application is requested.

In the Office Action, claims 1-22 were rejected under 35 USC §112, first paragraph as failing to comply with the enablement requirement. In response, Applicant has the following comments.

The example illustrated in Table 1 at page 7 of the description as filed demonstrates that the survival rate of female rats that have undergone ovariectomy is significantly increased if they are administered 2-methylene-19-nor-(20S)-1α,25-dihydroxy-vitamin D_3, hereinafter "2MD". The experiment set forth on pages 6 and 7 of the specification was carried on for 7-1/2 months with one-half the animals receiving a vehicle and the other half of the animals receiving 2MD. During the course of this 7-1/2 month experiment, all of the animals receiving 2MD survived and were in good health. In contrast, at least three of the control animals failed to survive due to the development of mammary tumors. A fourth died of unknown causes. These data clearly show that all of the treated animals survived whereas a significant number of the untreated animals failed to survive due to the development of cancerous breast tumors. Thus, Applicant believes the data illustrate increased life expectancy, and thus the data support claims 1-5 as filed.

In addition, since the animals were all retired female breeder rats, 12 months of age or older and were ovariectomized, Applicant believes the data further illustrate the ability of 2MD to increase the life expectancy of females lacking estrogen. Thus, Applicant believes the data supports claims 6-11 as filed.

Claim 12 has been amended to limit the method to the treatment of "breast" cancer instead of just broadly to the treatment of "a cancer." These data contained in the specification illustrate that untreated animals developed breast tumors whereas animals

treated with 2MD did not. Therefore, Applicant believes these data support a claim to the inhibition of tumorogenesis in the treatment of breast cancer.

In the Office Action, claims 12-22 were rejected under the Doctrine of Obviousness Type Double Patenting as being unpatentable over claims 49-58 of co-pending Application No. 10/780,103. The '103 application is directed toward the 26,27-dihomo homolog of 2MD. In other words, in the present patent application, the claimed 2MD compound has one less methyl group at the 26 and 27 carbon positions in the side chain than the 26,27-dihomo compound described in the '103 application. The Examiner has indicated that since homologs are known to have similar properties, and since the '103 application also claims a method of treating cancerous diseases, the presently claimed method described in claims 12-22 would have been obvious to one skilled in the art. In response, Applicant has the following comments.

In the present patent application Serial No. 10/669,990, the vitamin D compound disclosed is 2-methylene-19-nor-20(S)-1α,25-dihydroxyvitamin D_3 (referred to as 2MD). This compound and its biological activity are disclosed in U.S. Patent 5,843,928 issued December 1, 1998. As can be seen from the '928 patent, especially from the data in Table 1 therein, and the description at column 15, line 63 through column 16, line 11, the compound 2MD has bone calcium mobilization activity that is greater than 1α,25-dihydroxyvitamin D_3, but has intestinal calcium transport activity which is less than 1α,25-dihydroxyvitamin D_3. In contrast, the compound 20(S)-1α,25-dihydroxy-2-methylene-26,27-dihomo-19-nor-vitamin D_3 covered by the method of claims 49-58 in the '103 application, has both bone calcium mobilization activity and intestinal calcium transport activity that is greater than 1α,25-dihydroxyvitamin D_3. Applicant refers the Examiner to the data contained in Table 4 found at the bottom of page 28 of the '103 patent application. These data clearly illustrate that the 26,27-dihomo compound claimed in claims 49-58 has different and unexpected calcemic activity from the compound 2MD claimed in the present patent application. Thus, although one skilled in the art would

expect the homologs to have similar properties due to their similar structures, these data clearly demonstrate that they have different calcemic activities.

Accordingly, Applicant believes the Examiner should withdraw the obvious type double patenting rejection of claims 12-22.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By _____

Thomas M. Wozny
Reg. No. 28,922
(414) 271-7590

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202